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November 25, 2003

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Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Group Art Unit 1614**

Re: U.S. Utility Patent Application  
Appl. No.: 10/644,783; Filed: August 21, 2003  
For: **Sodium Channel Blocker Compositions and the Use Thereof**  
Inventor: Nancy C. LAN  
Our Ref: 1483.0370003/JMC/THN

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Form PTO-1449 (20 pages);
3. Copies of cited documents AS6; AR8; AS11; AS13; AT13; AT14; AT16; AS19; AT19; and AR20; and
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
November 25, 2003  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "John M. Covert". The signature is fluid and cursive, with the first name "John" being more prominent.

John M. Covert  
Attorney for Applicant  
Registration No. 38,759

Enclosures

::ODMA\MHODMA\SKGF\_DC1;202222;1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Nancy C. LAN

Appl. No.: 10/644,783

Filed: August 21, 2003

For: **Sodium Channel Blocker  
Compositions and the Use Thereof**

Confirmation No.: 6918

Art Unit: 1614

Examiner: To Be Assigned

Atty. Docket: 1483.0370003/JMC/THN

Information Disclosure Statement

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents **AS6, AR8, AS11, AS13, AT13, AT14, AT16, AS19, AT19** and **AR20** are provided. Copies of all cited U.S. Patents are not required, as the filing date of this application is after June 30, 2003. Copies of all other documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/971,007, filed October 5, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

In accordance with 37 C.F.R. § 1.98(a)(3), Applicant's undersigned representative submits the following, in regards to non-English language documents **AL2, AN3** and **AM4** cited on Form PTO-1449:

Document **AL2**, French Patent Application No. FR 2 756 738, is in the French language. U.S. Patent No. 6,207,685 B1 claiming priority from FR 2 756 738 is cited as document **AJ2**.

Document **AN3**, German Patent Application No. DE 198 02 327 A1, is in the German language. An English language abstract of document **AN3** is cited as document **AT17**.

Document **AM4**, PCT Patent Application No. WO 99/61408, is in the Spanish language. The corresponding European Patent Application No. EP 1 083 164 is cited as document **AL5**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicant has listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120, 11380G37, 38 (May 19, 1992).

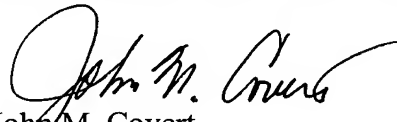
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



John M. Covert  
Attorney for Applicant  
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Date: Nov 25, 2003

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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 1483.0370003/JMC/THN	APPLICATION NO. 10/644,783
	APPLICANT Nancy C. LAN	
	FILING DATE August 21, 2003	GROUP 1614

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	4,024,175	05/17/1977	Satzinger et al.			12/31/1975
	AB1	4,087,544	05/02/1978	Satzinger et al.			04/28/1977
	AC1	4,602,017	07/22/1986	Sawyer et al.			02/27/1984
	AD1	4,894,476	01/16/1990	Butler et al.			05/02/1988
	AE1	5,025,035	06/18/1991	Wallace			10/12/1990
	AF1	5,179,109	01/12/1993	Kamenka et al.			06/21/1990
	AG1	5,236,957	08/17/1993	Dostert et al.			01/25/1991
	AH1	5,256,669	10/26/1993	Askanazi et al.			08/07/1992
	AI1	5,330,515	07/19/1994	Rutecki et al.			06/17/1992
	AJ1	5,446,066	08/29/1995	Varasi et al.			03/22/1994
	AK1	5,449,692	09/12/1995	Varasi et al.			03/22/1994

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 96/40628	12/19/1996	WIPO			Yes No
	AM1	WO 97/05102	02/13/1997	WIPO			Yes No
	AN1	WO 98/07447	02/26/1998	WIPO			Yes No
	AO1	WO 98/08842	03/05/1998	WIPO			Yes No
	AP1	WO 98/19674 A2	05/14/1998	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	<u>1</u>	Backonja, M., et al., "Gabapentin for the Symptomatic Treatment of Painful Neuropathy in Patients With Diabetes Mellitus," <i>JAMA</i> 280:1831-1836, The American Medical Association (December 1998)	
AS	<u>1</u>	Bennett, G.J., "Neuropathic Pain: An Overview," in <i>Molecular Neurobiology of Pain</i> 9:109-113, Borshook, D., ed., IASP Press, Seattle (1997)	
AT	<u>1</u>	Bensimon, G., et al., "A Controlled Trial of Riluzole in Amyotrophic Lateral Sclerosis," <i>New England J. Med.</i> 330:585-591, The Massachusetts Medical Society (1994)	

EXAMINER	DATE CONSIDERED
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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



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August 21, 2003GROUP  
1614

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	5,660,861	08/26/1997	Jao et al.			05/12/1995
	AB2	5,712,277	01/27/1998	Nakamura-Craig et al.			07/15/1996
	AC2	5,741,818	04/21/1998	Dimmock			06/07/1995
	AD2	5,891,849	04/06/1999	Amstutz et al.			11/07/1997
	AE2	5,905,069	05/18/1999	Borsook et al.			01/26/1998
	AF2	5,942,510	08/24/1999	Floyd et al.			06/20/1996
	AG2	6,113,915	09/05/2000	Aoki et al.			10/12/1999
	AH2	6,180,624 B1	01/30/2001	Hill			02/25/1999
	AI2	6,187,338 B1	02/13/2001	Caruso et al.			02/22/1999
	AJ2	6,207,685 B1	03/27/2001	Lallement et al.			01/11/1999
	AK2	6,242,488 B1	06/05/2001	Bueno et al.			05/09/2000

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	FR 2 756 738	06/12/1998	France			X Yes No
	AM2	WO 98/28255	07/02/1998	WIPO			Yes No
	AN2	WO 98/19674 A3	07/16/1998	WIPO			Yes No
	AO2	WO 98/43964	10/08/1998	WIPO			Yes No
	AP2	WO 98/47869	10/29/1998	WIPO			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Beydoun, A., "Postherpetic Neuralgia: Role of Gabapentin and Other Treatment Modalities," <i>Epilepsia</i> 40(Suppl. 6):S51-S56, Lippincott Williams & Wilkins (October 1999)
	AS	2	Blinder, B.J., et al., "Advances in Mood Stabilizing Medications," <i>West. J. Med.</i> 169:39-40, BMJ Publishing (1998)
	AT	2	Boyce, S., et al., "Selective NMDA NR2B antagonists induce antinociception without motor dysfunction: correlation with restricted localisation of NR2B subunit in dorsal horn," <i>Neuropharmacology</i> 38:611-623, Pergamon and Elsevier Science Ltd. (May 1999)

EXAMINER

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	APPLICANT Nancy C. LAN	
	FILING DATE August 21, 2003	GROUP 1614

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3	6,281,211 B1	08/28/2001	Cai et al.			09/21/2000
	AB3	6,290,986	09/18/2001	Murdock et al.			06/29/1998
	AC3	6,326,374 B1	12/04/2001	Magnus et al.			06/18/1999
	AD3	6,326,385 B1	12/04/2001	Wickenden et al.			08/04/2000
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3	WO 99/12537	03/18/1999	WIPO			Yes No
	AM3	WO 99/26614	06/03/1999	WIPO			Yes No
	AN3	DE 198 02 327 A1	07/29/1999	Germany			Yes X No
	AO3	WO 99/37296	07/29/1999	WIPO			Yes No
	AP3	WO 99/39712	08/12/1999	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>3</u>	Brown, C.M., et al., "Neuroprotective properties of lifarizine compared with those of other agents in a mouse model of focal cerebral ischaemia," <i>British J. Pharmacol.</i> 115:1425-1432, Stockton Press (1995)
	AS	<u>3</u>	Bryans, J.S., and Wustrow, D.J., "3-Substituted GABA Analogs with Central Nervous System Activity: A Review," <i>Med. Res. Rev.</i> 19:149-177, John Wiley & Sons, Inc. (March 1999)
	AT	<u>3</u>	Buchan, A.M., et al., "AMPA Antagonists: Do They Hold More Promise for Clinical Stroke Trials Than NMDA Antagonists?," <i>Supplement I, Stroke</i> 24:I148-I152, American Heart Association (1993)

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1614**U.S. PATENT DOCUMENTS**

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**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL4	WO 99/44610	09/10/1999	WIPO			Yes No
	AM4	WO 99/61408	12/02/1999	WIPO			X Yes No
	AN4	WO 00/02562	01/20/2000	WIPO			Yes No
	AO4	WO 00/02592	01/20/2000	WIPO			Yes No
	AP4	WO 00/57877	10/05/2000	WIPO			Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>4</u>	Canavero, S., et al., "The riddle of trigeminal neuralgia," Pain 60:229-231, Elsevier Science B.V. (1995)
	AS	<u>4</u>	Carrazana, E.J., and Schachter, S.C., "Alternative uses of lamotrigine and gabapentin in the treatment of trigeminal neuralgia," Neurology 50:1192, The American Academy of Neurology (April 1998)
	AT	<u>4</u>	Catterall, W.A., "Common modes of drug action on Na <sup>+</sup> channels: local anesthetics, antiarrhythmics and anticonvulsants," Trends Pharmacol. Sci. 8:57-65, Elsevier Science Publishers B.V. (1987)

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**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL5	EP 1 083 164	03/14/2001	Europe			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>5</u>	Catterall, W.A., "Neurotoxins That Act on Voltage-sensitive Sodium Channels in Excitable Membranes," <i>Ann. Rev. Pharmacol. Toxicol.</i> 20:15-43, Annual Reviews Inc. (1980)
	AS	<u>5</u>	Catterall, W.A., "Structure and Function of Voltage-Sensitive Ion Channels," <i>Science</i> 242:50-61, The American Association for the Advancement of the Science (1988)
	AT	<u>5</u>	Chapman, V., et al., "Effects of systemic carbamazepine and gabapentin on spinal neuronal responses in spinal nerve ligated rats," <i>Pain</i> 75:261-272, Elsevier Science B.V. (April 1998)

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>6</u>	Creveling, C.R., et al., "Batrachotoxin-Induced Depolarization and [ <sup>3</sup> H]Batrachotoxinin-A 20 $\alpha$ -Benzoate Binding in a Vesicular Preparation from Guinea Pig Cerebral Cortex," <i>Mol. Pharmacol.</i> 23:350-358, The American Society for Pharmacology and Experimental Therapeutics (1983)
	AS	<u>6</u>	Czuczwar, S.J., and Przesmycki, K., "Felbamate, Gabapentin and Topiramate as Adjuvant Antiepileptic Drugs in Experimental Models of Epilepsy," <i>Polish J. Pharmacol.</i> 53:65-68, Polish Academy of Sciences (2001)
	AT	<u>6</u>	De Sarro, G., et al., "Gabapentin Potentiates the Antiseizure Activity of Certain Anticonvulsants in DBA/2 Mice," <i>Eur. J. Pharmacol.</i> 349:179-185, Elsevier Science (1998)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>7</u>	Denicoff, K.D., et al., "Efficacy of Carbamazepine Compared With Other Agents: A Clinical Practice Survey," <i>J. Clin. Psychiatry</i> 55:70-76, Physicians Postgraduate Press, Inc. (1994)
	AS	<u>7</u>	Dichter, M.A., et al., "Drug Therapy: New Antiepileptic Drugs," <i>New Engl. J. Med.</i> 334:1583-1590, Massachusetts Medical Society (1996)
	AT	<u>7</u>	Field, M.J., et al., "Gabapentin and pregabalin, but not morphine and amitriptyline, block both static and dynamic components of mechanical allodynia induced by streptozocin in the rat," <i>Pain</i> 80:391-398, Elsevier Science B.V. (March 1999)

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>8</u>	Goldberg, I., and Green, B., "Focus on Gabapentin," <i>Focus</i> 8:1-6, Priory Lodge Education Ltd. (1997) from <a href="http://www.priory.com/focus8.htm">http://www.priory.com/focus8.htm</a>
	AS	<u>8</u>	Graham, S.H., et al., "A Dose-Response Study of Neuroprotection Using the AMPA Antagonist NBQX in Rat Focal Cerebral Ischemia," <i>J. Pharmacol. Exp. Therap.</i> 276:1-4, Williams & Wilkins (1996)
	AT	<u>8</u>	Graham, S.H., et al., "Neuroprotective Effects of a Use-Dependent Blocker of Voltage-Dependent Sodium Channels, BW619C89, in Rat Middle Cerebral Artery Occlusion," <i>J. Pharmacol. Exp. Therap.</i> 269:854-859, Williams & Wilkins (1994)

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>2</u>	Gurney, et al., "Benefit of Vitamin E, Riluzole, and Gabapentin in a Transgenic Model of Familial Amyotrophic Lateral Sclerosis," <i>Ann. Neurol.</i> 39:147-157, The American Neurological Association (1996)
	AS	<u>2</u>	Hamill, O.P., et al., "Improved Patch-Clamp Techniques for High-Resolution Current Recording from Cells and Cell-Free Membrane Patches," <i>Pfluegers Arch</i> 391:85-100, Springer International (1981)
	AT	<u>2</u>	Hoekstra, M.S., et al., "Chemical Development of CI-1008, an Enantiomerically Pure Anticonvulsant," <i>Org. Process Res. Dev.</i> 1:26-38, American Chemical Society and Royal Society of Chemistry (1997)

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.  
1483.0370003/JMC/THNAPPLICATION NO.  
10/644,783APPLICANT  
Nancy C. LANFILING DATE  
August 21, 2003GROUP  
1614

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	AR	<u>10</u>	Hunskaar, S., et al., "Formalin test in mice, a useful technique for evaluating mild analgesics," <i>J. Neurosci. Methods</i> 14:69-76, Elsevier Science Publishers B.V. (1985)
	AS	<u>10</u>	Iwasaki, Y., et al., "CNQX prevents spinal motor neuron death following sciatic nerve transection in newborn rats," <i>J. Neuro Sci.</i> 134:21-25, Elsevier Science B.V. (1995)
	AT	<u>10</u>	Kim, S.H., et al., "An experimental model for peripheral neuropathy produced by segmental spinal nerve ligation in the rat," <i>Pain</i> 50:355-363, Elsevier Science Publishers B.V. (1992)

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	AR	<u>11</u>	Kingery, W.S., "A critical review of controlled clinical trials for peripheral neuropathic pain and complex regional pain syndromes," <i>Pain</i> 73:123-139, Elsevier Science B.V. (1997)
	AS	<u>11</u>	Kudoh, A., et al., "Effect of Carbamazepine on Pain Scores of Unipolar Depressed Patients with Chronic Pain: A Trial of Off-On-Off-On Design," <i>Clin. J. Pain</i> 14:61-65, Lippincott-Raven Publishers (1998)
	AT	<u>11</u>	Low, P.A., and Dotson, R.M., "Symptomatic Treatment of Painful Neuropathy," <i>JAMA</i> 280:1863-1864, The American Medical Association (December 1998)

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	AR	<u>12</u>	Lunardi, G., et al., "Clinical effectiveness of lamotrigine and plasma levels in essential and symptomatic trigeminal neuralgia," <i>Neurology</i> 48:1714-1717, Lippincott-Raven Publishers (1997)
	AS	<u>12</u>	Magnus, L., "Nonepileptic Uses of Gabapentin," <i>Epilepsia</i> 40(Suppl. 6):S66-S72, Lippincott Williams & Wilkins (October 1999)
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	AR	<u>13</u>	Ohizumi, Y., et al., "Specific Inhibitors of [ <sup>3</sup> H] Saxitoxin Binding to Skeletal Muscle Sodium Channels by Geographutoxin II, a Polypeptide Channel Blocker," <i>J. Biol. Chem.</i> 261:6149-6152, The American Society of Biological Chemists, Inc. (1986)
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	AR	<u>14</u>	Rowbotham, M., et al., "Gabapentin for the Treatment of Postherpetic Neuralgia," JAMA 280:1837-1842, The American Medical Association (December 1998)
	AS	<u>14</u>	Sheardown, M.J., et al., "AMPA, but not NMDA, receptor antagonism is neuroprotective in gerbil global ischaemia, even when delayed 24 h," Eur. J. Pharmacol. 236:347-353, Elsevier Science Publishers B.V. (1993)
	AT	<u>14</u>	Sist, T.C., et al., "Experience With Gabapentin for Neuropathic Pain in the Head and Neck: Report of Ten Cases," Reg. Anesth. 22:473-478, The American Society of Regional Anesthesia (1997)

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	AR	<u>15</u>	Solaro, C., et al., "A patient with multiple sclerosis and Down's syndrome with a rare paroxysmal symptom at onset," <i>Eur. J. Neurol.</i> 6:505-507, Lippincott Williams & Wilkins (July 1999)
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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>16</u>	Verdoorn, T.A., et al., "Functional Properties of Recombinant Rat GABA <sub>A</sub> Receptors Depend upon Subunit Composition," <i>Neuron</i> 4:919-928, Cell Press (1990)
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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>17</u>	Wrathall, J.R., et al., "Amelioration of Functional Deficits from Spinal Cord Trauma with Systemically Administered NBQX, an Antagonist of Non-N-methyl-D-aspartate receptors," <i>Exp. Neurology</i> 137:119-126, Academic Press, Inc. (1996)
	AS	<u>17</u>	Yoon, M.H., and Yaksh, T.L., "Evaluation of Interaction between Gabapentin and Ibuprofen on the Formalin Test in Rats," <i>Anesthesiology</i> 91:1006-1013, Lippincott Williams & Wilkins, Inc. (October 1999)
	AT	<u>17</u>	Dialog File 351, Accession No. 12613976, Derwent WPI English language abstract for DE 198 02 327 A1 (Document AN3)

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>18</u>	List of abstracts concerning SCRIIP 1773:14 (1992) provided by client
	AS	<u>18</u>	List of abstracts concerning SCRIIP 1870:8 (1993) provided by client
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	AN						Yes No
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	AP						Yes No

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	AR	<u>19</u>	United States Application No. 60/126,553, Hogenkamp et al., filed March 26, 1999
	AS	<u>19</u>	Attal, N., "Antiepileptic drugs in the treatment of neuropathic pain," <i>Exp. Rev. Neurotherapeutics</i> 1:199-206, Future Drugs Ltd. (2001)
	AT	<u>19</u>	Bennett, G.J., "Neuropathic Pain: New Insights, New Interventions," <i>Hospital Practice</i> 33:95-98,101-104,107-110,113-114, The McGraw-Hill Companies, Inc. (1998)

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